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UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SURGICAL INSTRUMENT SERVICE COMPANY, INC.,

Plaintiff/
Counterclaim-Defendant

vs.

INTUITIVE SURGICAL, INC.,

Defendant/
Counterclaimant.

Case No.: 3:21-cv-03496-VC

OPPOSITION OF DEFENDANT/COUNTERCLAIMANT INTUITIVE SURGICAL, INC. TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND CROSS-MOTION FOR SUMMARY JUDGMENT

Hearing Date: June 8, 2023
Hearing Time: 1:00 p.m.
Hearing Place: Courtroom 5

Judge: The Honorable Vince Chhabria

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes and Regulations

NOTICE OF MOTION AND MOTION

TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE that on June 8, 2023, at 1:00 PM, or as soon thereafter as available, in the courtroom of the Honorable Vince G. Chhabria, at 450 Golden Gate Avenue, Courtroom 5, 17th Floor, San Francisco, CA 94102, Defendant/Counterclaimant Intuitive Surgical, Inc. ("Intuitive") will and hereby does move for an order granting summary judgment in favor of Intuitive on the complaint of plaintiff Surgical Instrument Service Company, Inc. ("SIS"). This Motion is based on the Memorandum of Points and Authorities provided below, the accompanying Declarations of Kathryn Cahoy, Dave Rosa, and Loren Smith, with attached exhibits, any reply or other supplemental briefing and/or evidence submitted, and the oral argument of counsel.

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION AND STATEMENT OF ISSUES

SIS brings this suit because Intuitive objected when a third party for which SIS was a distributor tried to hack into Intuitive's complex, precision surgical instruments to bypass use limits on the instruments that were carefully designed and tested by Intuitive and cleared by the Food & Drug Administration ("FDA") to protect the health and safety of surgical patients. Intuitive has taken the position that the modification of its instruments for this purpose cannot lawfully occur without FDA clearance. FDA agrees and has repeatedly said so.

SIS's motion for partial summary asks the Court to ignore FDA's numerous and consistent statements and actions on this question over a period of nearly a decade, as well as the plain language of the applicable regulations, because FDA has not issued formal "guidance" that interprets those regulations in *other* contexts, thus somehow rendering FDA's true views about the application of the regulations to *this* situation open to debate.

The question of whether the activity at issue here required FDA clearance – which SIS's motion addresses only in the context of Intuitive's counterclaims (and one defense) but also goes to the heart of SIS's claims against Intuitive – is unquestionably a legal one, and it is not ambiguous. No one disputes that the statute and regulations require FDA clearance for "remanufacturing" of medical devices; the regulations state what remanufacturing is; the undisputed record shows what the modifications at issue

consist of; and regardless of whether, as SIS suggests, the line between "remanufacture" and "repair" is unclear in *other* contexts, it is perfectly clear here.

Because the activity that is the subject of this action was barred by the applicable regulatory regime, SIS cannot establish causation of antitrust injury. SIS's antitrust claims also fail for another fundamental reason: the undisputed record shows that Intuitive had a reasonable basis to conclude that its actions were justified by imperatives recognized as legitimate by the governing regulatory authority. The antitrust laws condemn only *unreasonable* restraints of trade. *Ohio v. Amer. Express Co.*, 138 S. Ct. 2274, 2284 (2018). Nothing Intuitive is alleged to have done satisfies this standard. Nor did Intuitive's statements about the need for FDA clearance violate the Lanham Act.

SIS's motion for partial summary judgment should be denied, and the Court should enter summary judgment for Intuitive on all of SIS's claims.

II. STATEMENT OF UNDISPUTED FACTS[1]

A. The Da Vinci

Intuitive manufactures sophisticated medical devices used to perform surgery. Its da Vinci systems are often referred to as "robotic" surgical systems, as they allow a surgeon to operate from a console that permits the surgeon to control "EndoWrist" surgical instruments attached to mechanical arms suspended above the patient. Rosa Dec. ¶ 9. EndoWrists are inserted through small incisions and can perform extremely precise, fine-tuned movements, allowing surgery to be done in a "minimally invasive" manner. The surgeon views a video feed from a tiny camera mounted on one of the arms. *Id.* ¶ 9. Da Vinci systems allow surgeons to perform procedures with significantly reduced trauma and improved patient outcomes compared with other modes of surgery, including fewer complications and faster recovery times. *Id.* ¶ 9.

The first da Vinci systems were introduced commercially in the United States in 2000, after years of innovation and exhaustive testing, followed by detailed review by FDA, which classifies a da

[1] Some sections of the discussion below are similar, or even identical, to corresponding sections of the Statement of Undisputed Facts in Intuitive's opposition and cross-motion for summary judgment in *In re: Da Vinci Surgical Robot Antitrust Litigation*, No. 3:21-cv-03825-VC ("Hospital Case"), also pending before this Court. Variations arise from differences in the claims asserted in the two cases, in the arguments made by the respective plaintiffs, and in the facts that are pertinent to some of those arguments.

Vinci system and the instruments used with it as Class II medical devices that require "510(k)" clearance before they can be marketed and used on patients. *Id.* ¶ 8; *see* Cahoy Dec. Ex. 10 ¶¶ 144, 148. FDA has granted Intuitive 510(k) clearance for all EndoWrists used with da Vinci systems. That FDA clearance, and the resulting labeling of the devices, reflect use restrictions developed through extensive testing and reviewed by FDA for reasonable assurance of safety and effectiveness. Rosa Dec. ¶ 23; Cahoy Dec. Ex. 10 ¶ 75-76.

Like many innovative products, da Vinci systems have evolved over time, and Intuitive has introduced new models from time to time, with support eventually being phased out for outdated models. The "Si" systems were introduced in 2009; Intuitive ceased selling new Si systems in 2018 and is expecting to cease support for them, including the sale of new S/Si EndoWrists, in 2024, ten years after introducing the successor Xi model. Rosa Dec. ¶ 11; Cahoy Dec. Ex. 2 at 172:13-174:12. The Xi model offers a number of improvements over the previous generation, and, as a result, can be used for a broader array of procedures. Cahoy Dec. Ex. 2 at 27:23-29:2, 136:18-137:22, Ex. 51 at 97:17-98:6, Ex. 74 at 61:13-62:9. The models primarily used today in the United States are the Xi, introduced in 2014, and the X, introduced in 2017. Rosa Dec. ¶ 11. The X and Xi systems use Generation 4 EndoWrists; the S and Si systems use older-design Generation 3 EndoWrists. *Id.* ¶ 11. Intuitive has numerous patents on innovations embodied in da Vinci systems and EndoWrists. *Id.* ¶ 12.

B. Use Limits on EndoWrists

One of the primary innovations of the da Vinci is the unique design of EndoWrists, which mimic and even exceed the range of motion of the human wrist, allowing the surgeon to move an instrument easily inside the body to desired angles with great precision. Rosa Dec. ¶ 24. This feature requires use of fine wire cables that thread through a complex pulley system. *Id.* ¶ 24. This design gives the surgeon tremendous flexibility, but at the cost of making the instruments susceptible to wear and tear with repeated use. Unlike traditional surgical instruments, EndoWrists can fail after only a modest number of uses. *Id.* ¶ 27. Failure can occur in multiple ways, including (among others) metal fatigue of the fine wire cables, friction in the intricate pulley system, and failure of the apparatus to maintain the needed precision of movement. *Id.* ¶ 27; *see* Cahoy Dec. Ex. 75 ¶¶ 34, 73, Ex. 4 at 38:17-47:12. The result of such failures mid-surgery can range from modest (requiring the instrument to be withdrawn from the

body and replaced) to serious (if, for example, tiny pieces fall into the body) to catastrophic (if, for example, the wrist feature fails and leads to unwanted motion just as the surgeon is performing a task adjacent to a major blood vessel). Rosa Dec. ¶ 27; *see also* Cahoy Dec. Ex. 9 at 48:21-51:25, Ex. 5 at 55:3-25, Ex. 4 at 165:7-169:13, Ex. 76 ¶ 20, 42.

Because of the potential implications of EndoWrist failure, the useful life of EndoWrists has long – going back more than 20 years – been a focus of exhaustive testing programs, which formed the foundation for the required safety demonstrations to FDA. Rosa Dec. ¶ 28. It was clear from the beginning that use limits would be needed for EndoWrists, with a reasonable margin of safety. The nature and extent of those limits required evaluation, not just of the wear and tear the instruments would experience in typical surgical procedures, but also of the stresses associated with the rigorous cleaning and sterilization processes required for each use. *Id.* ¶ 29; *see also* Cahoy Dec. Ex. 75 ¶¶ 39, 119-20. Over a period of years, Intuitive performed extensive testing on EndoWrists to evaluate the number of uses that could be tolerated without exceeding statistical targets for failure. Rosa Dec. ¶ 29; *see* Cahoy Dec. Ex. 5 at 31:9-32:15. The resulting data, along with the use limits generated based on the data, were submitted to FDA in Intuitive's 510(k) submissions, with the use limits identified as prerequisites for the regulatory clearance that was sought and granted. Rosa Dec. ¶ 31.[2] EndoWrists were described to, and cleared by, FDA as "limited use" instruments containing use counters that cause each EndoWrist to cease functioning after its final cleared use. *Id.* ¶ 31; *see* Cahoy Dec. Ex. 10 ¶¶ 75-76. For most S/Si instruments, Intuitive proposed, and FDA cleared, a limit of ten uses. Rosa Dec. ¶ 33.[3]

[2] SIS asserts that the use limits were "set" by Intuitive's "marketing department." SIS Mot., Dkt. 127, at 3. This is both a misstatement and a red herring. Intuitive's marketing group provided input on the use limits that were selected – but the primary content of that input, particularly in the early days, was strong encouragement to redesign EndoWrists under development to allow *more* uses than early testing supported. Rosa Dec. ¶ 32; *see* Cahoy Dec. Ex. 5 at 35:9-36:16. Most importantly, the undisputed record shows that the use limits were validated by years of testing performed by Intuitive's engineers.

[3] Recently, Intuitive has sought and obtained FDA clearance for "extended" use limits for certain X/Xi EndoWrists that range as high as 18 uses. Rosa Dec. ¶ 33. These extended use limits were made possible by years of incremental product improvements in the more advanced X/Xi instruments that were not applicable to the older S/Si instruments, which remain prone to earlier failure. *Id.* ¶ 34; Cahoy Dec. Ex. 4 at 171:20-172:20, Ex. 66 at 97:6-13; 113:11-116:13; 197:15-201:3, Ex. 73 at 232:18-235:3.

Each EndoWrist has a computer chip that tracks critical information about the instrument, including the number of times it has been used. The chip is programmed to render the instrument nonfunctional after it has had the maximum allowed number of uses. This prevents a user from inadvertently (or otherwise) exceeding the number of approved uses for the instrument. *Id.* ¶ 36. The computer chip used for this purpose in S/Si EndoWrists is called the "Dallas" chip and communicates with the da Vinci system through a physical connection. *Id.* ¶ 37; Cahoy Dec. Ex. 8 at 108:24-109:15, Ex. 9 at 20:1-21:5. For X/Xi systems, Intuitive upgraded to a wireless connection; this required the chip to be encrypted for security purposes to avoid tampering. Rosa Dec. ¶ 37; Cahoy Dec. Ex. 8 at 121:14-122:7, Ex. 9 at 22:5-21, 30:9-17, 40:13-41:1.

SIS has no evidence to dispute that EndoWrists are subject to failure from wear-and-tear; nor does it have evidence that they can reliably be used indefinitely. Instead, the most SIS's technical expert offers is speculation that this safety issue could instead have been managed through some kind of complex monitoring of the specific length of time during which each instrument is used and the actions performed with it. This opinion is the subject of a pending *Daubert* motion. *See* Dkt. No. 120. Even SIS's expert is unable to dispute that (a) the use limits were preceded by years of exhaustive safety testing, (b) that they were cleared by FDA, and (c) nothing in Intuitive's decades of testing data indicates that EndoWrists could consistently be used safely and reliably for a substantially greater number of uses than they were cleared for. *See* Cahoy Ex. 75 ¶¶ 62-70, Ex. 10 § 75-101.

C. Intuitive's Sales to Hospitals

Each purchaser or lessor of a da Vinci enters into a contract with Intuitive, typically a Sales, Licensing and Service Agreement ("SLSA") or corresponding lease agreement; the terms of those contracts are heavily negotiated. *See* Rosa Dec. ¶ 21. Although the language of the contracts varies, they typically prohibit customers from modifying, altering, or misusing the system and its components or manipulating the software. *See, e.g.*, Cahoy Dec. Ex. 11 at -5489-90 (§§ 3.4, 4, 5.2), Ex. 12 at -6316, -6318 (§§ 4, 5.2), Ex. 13 at -0653-54 (§§ 3.4, 4, 5.2). The agreements confirm that the da Vinci system should be used only with approved EndoWrists and provide that use of a non-approved instrument may give Intuitive the right to discontinue service. *E.g.*, *id.* Ex. 11 at -5490-91 (§§ 5.2(E), 10.1), Ex. 12 at -6318, -6320 (§§ 5.2(E), 10.1), Ex. 13 at -0654-56 (§§ 5.2(E), 10.1).

D. Third-Party Modifications of EndoWrists to Hack the Use Counters and Reactions from FDA

Sometime around 2014, a company called Rebotix decided it wanted to create a new business by hacking into EndoWrists to defeat the use counters.[4] Rebotix developed a computer chip called the "Interceptor" that could be inserted inside an Si EndoWrist to "intercept" the data in the Dallas chip's memory and fool the system into accepting a new use count starting at zero. *See id.* Ex. 14 at -1000. However, [redacted] *See id.* Ex. 15 at -2418-23. For example, [redacted] *Id.* Ex. 15 at -2421-22, Ex. 16 at 238:7-11.[5] Although Rebotix advertised that this reset could be performed multiple times to extend an instrument's life indefinitely in increments of 10, *see id.* Ex. 19 at 65:6-11, Ex. 20 at 171:1-8, 176:13-177:22, the record is devoid of testing data to confirm the accuracy of this claim.

In December 2014, [redacted] *See id.* Ex. 10 ¶ 103, Ex. 21. [redacted] *Id.* Ex. 22 at -7733. [redacted]

[4] There have been multiple affiliated entities operating under various iterations of the "Rebotix" name; for purposes of simplicity they are all referred to here as "Rebotix." Similarly, the names "Restore" and "Iconocare" are used to refer collectively to entities that operated with versions of those respective names and/or shared common ownership with those companies.

[5] Intuitive at one point considered instituting a program to refurbish used EndoWrists. Unlike the reset service sold by SIS and others, this program contemplated *full* refurbishment, including replacing the cables and other sensitive parts that were prone to failure after multiple uses. Rosa Dec. ¶ 38; Cahoy Dec. Ex. 17 at 40:7-12. The project was abandoned when it was determined that the cost of proper refurbishment would make the project not commercially feasible. Rosa Dec. ¶ 39; Cahoy Dec. Ex. 18 at 172:23-173:20. [redacted]

[redacted] *Id.* Ex. 23; *see also id.* Ex. 10 ¶ 108.

Rather than addressing the deficiencies identified by FDA, Rebotix withdrew its application. *Id.* Ex. 24. Rebotix moved to Panama and offered its modified instruments to customers outside the United States, beyond the jurisdiction of FDA. *Id.* Ex. 20 at 49:3-50:14. But after those operations were enjoined abroad, Rebotix decided to try again in the United States. *See id.* Ex. 25 at -2749, Ex. 26 at 166:5-12. Rebotix's new business model, beginning in 2018, was for hospitals to retain ownership of their used Si EndoWrists and hire Rebotix to modify the instruments. *See id.* Ex. 20 at 210:9-21, 227:10-23. Although the modification was identical to the remanufacturing process for which Rebotix had previously acknowledged the need for FDA clearance, Rebotix told customers that a loophole in the law allowed the clearance process to be skipped if legal title to the used instruments did not change. *Id.* Ex. 20 at 212:15-218:8, Ex. 27 at -4230.

Rebotix entered into a relationship with Restore Robotics ("Restore"), which was to market the Rebotix process to hospitals, buy the Interceptor chips from Rebotix, and modify the instruments. *See id.* Ex. 28. Rebotix terminated the contract in late 2019. *Id.* Ex. 20 at 132:12-21. Although the Restore arrangement was supposed to be exclusive, *id.* Ex. 28 at -0714 (§ 3.2), Rebotix also entered into an arrangement with SIS under which SIS would market the Rebotix service to hospitals and Rebotix would perform the modifications, *id.* Ex. 29 at 19:2-8, 33:22-34:4; *see* pp. 9-10 below.

In May 2018, a Rebotix distributor asked FDA for clarification after potential customers expressed concern about Rebotix's lack of FDA clearance. Cahoy Dec. Ex. 31 at -0336, Ex. 20 at 219:13-24. Consistent with its prior communications to Rebotix, FDA confirmed that 510(k) clearance was required, because "if the use-life counter is reset or extended past the number of available use lives, then the device specifications are changed," which would constitute "remanufactur[ing]." *Id.* Ex. 31 at -0335; *see id.* Ex. 32. In February 2020, FDA emailed Rebotix directly, confirming that "a 510(k) is needed before [Rebotix] continue[s] [its] operation." *Id.* Ex. 34 at -6955.

FDA contacted Rebotix again in November 2021, stating that it had received information that Rebotix "may be remanufacturing the da Vinci S EndoWrist Instruments," and seeking further

information. *Id.* Ex. 35 at -5417. Rebotix then engaged in an effort to persuade FDA that it did not need 510(k) clearance; those efforts were unsuccessful. *See id.* Exs. 36, 37. FDA wrote to Restore as well, stating that "a 510(k) is needed before you continue your operation," and seeking more information on Restore's activities. *Id.* Ex. 10 ¶ 223, Ex. 38 at -1256. Rather than respond, Restore informed the agency that it had elected to exit the business. *Id.* Ex. 38 at -1249.

Restore then enlisted a third party, Iconocare, to develop an alternative technology for resetting Si EndoWrists and – bowing to the inevitable – to submit an application for FDA clearance. *Id.* Ex. 39 at 204:16-205:17, 213:19-216:23. Iconocare hired contractors to develop an alternative technology and then, in February 2021, submitted a 510(k) application for that new process which differed from the Rebotix process in important respects. *Id.* Ex. 39 at 213:9-15, Ex. 75 § 141-50. That application was limited to just *one* reset (adding ten additional uses but no more) of *one* Si EndoWrist model. *Id.* Ex. 40 at -7816-18. After an extensive 19-month review process, during which FDA required Iconocare to perform additional testing and make adjustments to its process, on September 30, 2022, Iconocare received clearance on its limited application. In the course of granting this clearance, FDA again confirmed that the modification to reset the use counter constituted "remanufacturing" and required Iconocare to include a label on the device housing that it is "Remanufactured by" Iconocare. *Id.* Ex. 10 ¶¶ 129, 136, Ex. 41 at -0535, Ex. 42 at -6093.

E. Intuitive's Response to the Activities of Rebotix and Restore

Intuitive first became aware of third parties modifying Si EndoWrists through customer returns of broken EndoWrists.[6] An Intuitive team that is responsible for failure analysis disassembled some of the returned instruments and discovered that they had been modified with the insertion of what Intuitive later learned were Rebotix Interceptor chips. Rosa Dec. ¶ 41; Cahoy Dec. Ex. 5 at 76:4-17, Ex. 9 at 35:17-22.

Intuitive began to reach out to customers who were using remanufactured EndoWrists, explaining that the use limits are grounded in extensive safety testing, and that resetting the use counters

[6] As part of its commitment to quality and regulatory obligations, Intuitive maintains a Returned Materials Authorization ("RMA") process that provides liberal "no questions asked" warranty coverage for EndoWrists that are returned for almost any reason other than clear and unmistakable abuse. Rosa Dec. ¶ 40. Returned devices are carefully evaluated to assess and track the causes of any failures. *Id.*

could create significant safety concerns for patients. Rosa Dec. ¶ 42 & Ex. 2. Intuitive expressed the view that such modifications required FDA clearance. *Id.* ¶ 42. Intuitive also pointed out that use of remanufactured devices without the required FDA clearances would violate customers' contracts with Intuitive. *Id.* ¶¶ 42-43 & Ex. 2 at -0926-27.[7]

The record contains no evidence that Intuitive has interfered in any way with EndoWrist modification efforts done pursuant to a duly issued FDA clearance. To the contrary, to avoid any possibility of confusion, Intuitive has made clear that use of an FDA-cleared remanufactured EndoWrist does not breach any customer's contract or otherwise subject a customer to adverse action by Intuitive. *Id.* ¶ 45. Intuitive continues to take the position that tampering with an EndoWrist to reset its use counter through any means *not* cleared by FDA is both unlawful and potentially dangerous.

F. Plaintiff SIS

Plaintiff SIS offers repair services for a variety of traditional open and laparoscopic surgical instruments. Cahoy Dec. Ex. 30 at 11:20-25. Contrary to the allegations of its Complaint (*see* Dkt. No. 1 ¶ 5), SIS has never performed any repair or remanufacturing services on EndoWrists or other robotic-assisted surgical instruments. *Id.* Ex. 30 at 17:11-20, Ex. 29 at 33:22-34:4, 54:24-55:1. Instead, it operated briefly as a distributor for Rebotix.

Sometime in 2019, SIS learned of Rebotix's S/Si EndoWrist remanufacturing service and agreed informally to act as a distributor. *Id.* Ex. 29 at 19:2-8, 33:20-35:21. SIS and Rebotix never had a signed agreement formalizing their relationship. *Id.* Ex. 77 at 41:23-5, Ex. 78. SIS began marketing Rebotix's EndoWrist modification service under SIS branding in mid-2019, without telling customers it was not actually doing the work. SIS never performed an EndoWrist modification itself and never had the capability to do so; rather, Rebotix performed all the modifications. *Id.* Ex. 29 at 21:16-19, 33:22-34:4.

[7] SIS makes much of the fact that Intuitive also reached out to FDA to inform it that third parties were remanufacturing EndoWrists and encouraged the agency to look into that activity. *See* SIS Mot. at 7 (citing JVH Dec. Ex. 26, Dkt. No. 127.27). That letter made no mention of SIS. In any event, nothing in SIS's motion suggests the existence of any exception in this case to the *Noerr-Pennington* doctrine, which exempts communications of this kind with the government from challenge under the antitrust laws. *Kottle v. Northwest Kidney Ctrs.*, 146 F.3d 1056 (9th Cir. 1998).

SIS adopted Rebotix's marketing materials as its own by affixing the SIS name and logo to the materials and sharing them with prospective customers. *Id.* Ex. 29 at 62:15-63:19, Ex. 79 at 65:23-66:8. The representations in those materials included claims that the remanufactured EndoWrists would "meet the quality and functional needs of a new device," "function identically to the new OEM EndoWrist," and equate to "an original da Vinci manufactured device that has been repaired to original specifications." *Id.* Ex. 80 at -5120, -5124. SIS's repurposed materials also reflected a representation that the modification constituted a "repair" and required no FDA clearance. *Id.* at -5120. SIS did nothing to evaluate the veracity of any of these claims. *Id.* Ex. 29 at 63:10-65:8, Ex. 79 at 66:17-67:23. The repurposed Rebotix marketing documents also discussed validation and safety testing and a "complete technical file" purportedly supporting the remanufacturing process – none of which SIS ever saw. *Id.* Ex. 79 at 29:3-23. SIS itself conducted no testing or evaluation of Rebotix's remanufacturing process to determine whether it was safe, reliable, or effective. *Id.* Ex. 29 at 31:10-32:4, 68:15-77:25, Ex. 79 at 22:23-24:16, 30:3-32:11.

SIS's brief foray into the sale of Rebotix's remanufacturing services was limited to modification of 42 EndoWrists for six customers. *Id.* Ex. 81 § VI(E), Sched. 14.0. SIS has not sold any EndoWrist modifications since 2019. *Id.* Ex. 81 at Sched. 14.0, Ex. 79 at 22:13-17. The record does not indicate any communication between SIS and Intuitive during its short-lived operation as a Rebotix distributor. Intuitive's letters to customers that it learned were using remanufactured instruments did go to one of SIS's customers for Rebotix's remanufacturing process, Marin Hospital, and one entity in Arizona that SIS identifies as a potential customer. *Id.* Exs. 82, 83.

Eventually, Rebotix ceased collaboration with SIS. *Id.* Ex. 30 at 39:13-16, Ex. 29 at 18:18-19. SIS has since become involved instead with Restore, providing unspecified "support" for Restore's efforts to hack into and modify X/Xi EndoWrists. *Id.* Ex. 29 at 43:4-24. SIS has disclaimed interest in working with Restore on any S/Si EndoWrist reset business. *Id.* 43:10-14.[8]

[8] SIS and Restore have a separate business, not at issue in this case, that they refer to as a "recovery" service. This business involves attaching a tool to an EndoWrist to count the number of lives remaining and charging customers for 25% of the "value" of those remaining lives. Mr. Johnson's rosy claims of "monumental" interest (SIS Mot. at 6) referred to this program, which Intuitive has never challenged. Cahoy Dec. Ex. 29 at 43:19-47:12, Ex. 84 50:12-22, 53:9-15, 55:12-14, 58:6-23, 60:9-12, 61:4-10.

G. X/Xi EndoWrists

It is undisputed that the only commercial offerings for remanufacturing of EndoWrists have been for those used with the S/Si da Vinci systems. SIS's Complaint concedes that "EndoWrist repair [sic] is not currently possible" for Xi EndoWrists. Dkt. No. 1 ¶ 108. There is no evidence that SIS has ever tried to modify X/Xi instruments. Rebotix and Restore have both worked for years to find ways to hack the encryption in later-generation X/Xi EndoWrists to bypass their use counters, but the evidence indicates they have not succeeded. Cahoy Dec. Ex. 96 at 60:15-18, Ex. 94 at 8:13-9:4, 10:9-11:1, Ex. 20 at 100:5-25, Ex. 95 at 31:15-32:1. There is no evidence that anyone has ever developed a method to reset use counters on X/Xi EndoWrists; nor has anyone received FDA clearance for such a process.

Intuitive's X/Xi platform uses wireless technology to transmit communications between the X/Xi da Vinci systems and the attached EndoWrists. Instead of the hard-wired "Dallas" chip in older S/Si EndoWrists, X/Xi EndoWrists contain a radio frequency identification ("RFID") chip to communicate critical data to the system, including identification information, drive parameters, calibration, and use counts. *See id.* Ex. 8 at 56:4-60:9, 109:6-22; Rosa Dec. ¶ 37. The RFID chip provides significant improvements in design and performance compared to the prior generation, including "increased memory, faster data access, and improved reliability and endurance." Cahoy Dec. Ex. 85 ¶¶ 22, 56, 79. Wireless technology itself provides several benefits over wired systems, including increased consistency and resistance to physical damage and reduced manufacturing complexity. *Id.* Ex. 5 at 27:20-28:8, Ex. 85 ¶¶ 23, 57-59, Ex. 86 at 98:13-16.

With the benefits of wireless technology, however, come risks: hacking and cyberattacks. Wired communication systems are susceptible only to attackers with close physical proximity to the system, but wireless communication systems are also susceptible to remote attack – even from miles away. *Id.* Ex. 85 ¶¶ 20-21, 33-38, 41-45, 52, Ex. 10 ¶ 51, Ex. 90 at -6542, -6594. Interference with the X/Xi RFID chip communications could affect instrument calibration, drive parameters, and precision of movement, all of which could pose risks to patients. *Id.* Ex. 8 at 59:17-65:16, 110:10-23, Ex. 9 at 40:22-41:1, Ex. 10 ¶ 251, Ex. 85 at ¶¶ 52-53. To prevent such interference and following FDA guidance, Intuitive implemented cryptographic safety measures to protect the RFID chip's data and

communications. *Id.* Ex. 85 ¶¶ 52-53, 67, Ex. 10 ¶ 251, Ex. 90 at -6542; Rosa Dec. ¶ 37. Because FDA evaluates manufacturers' efforts to mitigate cybersecurity risks, *see* Cahoy Dec. Ex. 10 ¶¶ 246-54, FDA inquired into Intuitive's cybersecurity risk assessment and mitigation efforts for the X/Xi platform, *see id.* Ex. 85 ¶ 52, Ex. 10 ¶ 251, Ex. 91 at -9499-500. In response, Intuitive demonstrated that it implemented encryption, password protection, and security key measures. *Id.* Ex. 10 ¶ 251, Ex 85 ¶ 52, Ex. 90 at -6536, -6542, -6593-94, -6640-42.

Just as the encryption of the wireless connection prevents other kinds of hacking, it presents a barrier to entities like Rebotix and Restore that wish to hack into the RFID chip in X/Xi EndoWrists to tamper with the use counter. SIS, which apparently has ambitions to be a distributor for Restore, does not like this.

III. ARGUMENT

Rule 56 "mandates the entry of summary judgment … against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). "When the nonmoving party has the burden of proof," the movant need only show "an absence of evidence to support the nonmoving party's case." *Devereaux v. Abbey*, 263 F.3d 1070, 1076 (9th Cir. 2001). When the opposing party identifies evidence of a genuine dispute of fact material to a legal issue presented, summary judgment must be denied. *Lopez v. Smith*, 203 F.3d 1122, 1131 (9th Cir. 2000).

SIS's Complaint asserts four causes of action under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, as well as one under Section 43 of the Lanham Act, 15 U.S.C. § 1125. SIS's motion for partial summary judgment addresses only Intuitive's counterclaims and one affirmative defense; however, Intuitive's cross-motion on the same fundamental issue – the need for FDA clearance for the remanufacturing of EndoWrists – would dispose of all of SIS's claims. SIS's claims also fail for the independent reasons that (a) Intuitive's challenged actions are supported by recognized legitimate justifications and (b) the statement SIS challenges under the Lanham Act was not false and misleading – and there is no evidence of consumer deception.

A. The Governing Regulatory Scheme Precluded Remanufacturing of EndoWrists Without FDA Clearance.

1. SIS Cannot Establish that Any Action of Intuitive Caused It Antitrust Injury.

A necessary element of any antitrust claim is proof of proximate causation of antitrust injury. *Atlantic Richfield Co. v. USA Petrol. Co.*, 495 U.S. 328, 334 (1990); *Ass'n of Wash. Pub. Hosp. Dists. v. Philip Morris Inc.*, 241 F.3d 696, 701 (9th Cir. 2001). Antitrust injury is that which "flows from that which makes the conduct unlawful" and "is of the type the antitrust laws were intended to prevent." *City of Oakland v. Oakland Raiders*, 20 F.4th 441, 456 (9th Cir. 2021). Lacking the ability to make this showing, SIS cannot carry its burden of proof on causation of antitrust injury.

There is no evidence that SIS – or anyone else (other than Intuitive) – has ever had the desire or physical ability to manufacture and sell new surgical instruments that work with da Vinci systems. Instead, SIS's claims about restraints on competition in an alleged "market" for EndoWrists focus *solely* on its inability to sell a process that modifies Intuitive EndoWrists to hack their use counters. One of the fundamental problems with this theory is that, with one narrow and recent exception that is not relevant here, no third party has ever had the legal ability to perform such modifications. Antitrust injury cannot be proved where the claimed injury "is caused by a regulatory scheme rather than by the defendant's actions," as it is "beyond fair dispute" that "a regulatory or legislative bar can break the chain of causation in an antitrust case." *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 165-66 (3d Cir. 2017); *Modesto Irrig. Dist v. Pac. Gas & Elec. Co.*, 309 F. Supp. 2d 1156 (N.D. Cal. 2004), *aff'd* 158 F. App'x 807 (9th Cir. 2005) (plaintiff did not suffer antitrust injury when prevented from offering service for which it lacked regulatory approval).[9]

It is undisputed that EndoWrists are Class II medical devices that require 510(k) clearance from FDA. Rosa Dec. ¶ 8, 34; Cahoy Dec. Ex. 10 ¶¶ 144-48; *see* 21 U.S.C. §§ 360(k), 360c(a)(1)(B). This

[9] *See also Snake River Valley Elec. Ass'n v. PacifiCorp*, 357 F.3d 1042, 1050 n.8 (9th Cir. 2004); *RSA Media, Inc. v. AK Media Grp., Inc.*, 260 F.3d 10, 15 (1st Cir. 2001); *City of Pittsburgh v. W. Penn Power Co.*, 147 F.3d 256, 269 (3d Cir. 1998); *In re Canadian Imp. Antitrust Litig.*, 470 F.3d 785, 791 (8th Cir. 2006); *Realnetworks Inc. v. DVD Copy Control Ass'n, Inc.*, 2010 WL 145098, at *6 (N.D. Cal. Jan. 8, 2010); *Datel Holdings Ltd. v. Microsoft Corp*, 2010 WL 3910344, at *4 (N.D. Cal. Oct. 4, 2010); *PharmacyChecker.com v. Nat'l Ass'n of Bds. of Pharmacy*, 2022 WL 347669, at *3 (S.D.N.Y. Feb. 4, 2022).

requirement is equally applicable to the "remanufacture" of a device. A "remanufacturer" is defined under FDA regulations as "any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use," as reflected in the 510(k) submission for the device previously cleared by FDA. 21 C.F.R. § 820.3(w). A remanufacturer meets the definition of "manufacturer" and is thus subject to 510(k) requirements. *See* 21 C.F.R. § 820.3(o) (defining manufacturer to include anyone engaged in remanufacturing); 21 C.F.R. § 807.20 (requiring manufacturers to register and list with the FDA); 21 C.F.R. § 807.81(a)(3) (requiring 510(k) clearance for a "change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process").

Neither SIS nor any of the other purported "competitors" in SIS's proposed EndoWrist "market" – all of whom used Rebotix's technology – possessed 510(k) clearance for the modification of EndoWrists. Only one 510(k) clearance has ever been issued for such a modification, and that was to Iconocare, which in late 2022 obtained FDA clearance for a *different* technology used to perform a *single* reset of just *one* kind of Si EndoWrist. SIS has no involvement with Iconocare, and there is no evidence that Intuitive has interfered with Iconocare's ability to operate under its clearance.

Although the plaintiffs in the Hospital Case have asked this Court to hold that the hacking of EndoWrist use counters is *not* "remanufacturing," SIS does not go so far. Instead, it argues that the question is so unclear that it (and, presumably everyone else) was free to ignore the regulations and remanufacture EndoWrists at will without FDA clearance. But it is, and has long been, clear that the activity at issue *does* require FDA clearance.

For the better part of a decade – ever since the issue first arose – FDA has consistently made clear that modifications of EndoWrists to reset their use counters is remanufacturing that requires 510(k) clearance. FDA has communicated that position both to those who sought such clearance and to those who sought to evade doing so. *See* Cahoy Dec. Ex. 10 ¶¶ 217-19, 221-32, *see also, id.*, Ex. 31 at -0335, Ex. 34 at -6955, Ex. 35 at -5417, Ex. 38 at -1256, Ex. 64 at -5712, -5727. It has repeatedly warned the latter that they should not operate without 510(k) clearance. *E.g., id.* Ex. 34 at -6955, Ex. 38 at -1256,

Ex. 64 at -5727. FDA has even adopted a formal product "code" – signifying the need for 510(k) clearance – for a computer controlled surgical instrument that has been "remanufactured to extend its useful life as compared to what was originally defined by the original equipment manufacturer." *Id.* Ex. 10 ¶¶ 149-54 & fig. 3.

FDA's consistency on this subject is not undercut by SIS's disparagement of the FDA Team Lead who authored many of the communications by quoting the unsupported (and self-interested) opinion of a Rebotix witness that he was "not a particularly high level person." SIS Mot. at 18. There is no record evidence that any of the FDA officials who over the years told Rebotix, Restore, and Iconocare that what they were doing was remanufacturing were acting outside their authority. Nor is anything changed by the fact that one communication informed Rebotix that the determination was not a final *appealable* order. *See* SIS Mot. at 18. In that same communication, FDA identified for Rebotix ways in which it could have the determination reduced to a form it could appeal. Cahoy Dec. Ex. 37 at -5839, Ex. 10 ¶¶ 230-34. There is no record of Rebotix accepting that invitation.

SIS's motion does not assert the principal argument advanced by Rebotix for why it should not need 510(k) clearance, *i.e.*, that the instruments it remanufactured were not "held or offered for sale." SIS's decision may reflect its awareness that the Ninth Circuit has already rejected the interpretation of that language upon which Rebotix relied. *See United States v. Kaplan*, 836 F.3d 1199, 1208-11 (9th Cir. 2016).[10] Instead, SIS argues that FDA has never provided final "guidance" interpreting its regulations, leaving open the possibility that the modification of EndoWrists at issue might be considered "repairs" for which 510(k) clearance is not needed – even though FDA has consistently confirmed that the operative regulations say otherwise.

Rebotix's modifications were not "repairs." *See* Cahoy Dec. 10 ¶ 176, Ex. 65 at 18. An EndoWrist with an expired use counter is not broken and in need of repair – it is operating exactly as designed. The purpose of the Rebotix technology was to *bypass* the use limits that were an integral part of the instrument's safety design, as cleared by FDA. It "significantly changes the finished device's

[10] The Hospital Plaintiffs do offer this argument, which is discussed further in Intuitive's opposition and cross-motion in that case. SIS obliquely suggests that FDA may not have jurisdiction to regulate "hospital-owned devices," SIS Mot. at 21 n.14, but that argument is squarely rejected by *Kaplan*.

performance or safety specifications," as reflected in its existing FDA clearance and is therefore remanufacturing. 21 C.F.R. § 820.3(w); *see* Cahoy Dec. Ex. 31 at -0335.

SIS expends considerable space in its motion on legislative and other statements about the need for further "guidance" from FDA on where the line is properly drawn between "remanufacturing" and "service," as well as proposed legislation that would have expanded upon the existing regulatory definitions. *See* SIS Mot. at 9-19. But none of those materials addressed the application of the existing regulation to the remanufacturing of EndoWrists, which is far from ambiguous and on which FDA's position has long been clear. The mere fact that there are *other* processes that may be performed on *other* kinds of medical devices for which the line is unclear does not mean that it is obscure here. If one took at face value SIS's argument – that nothing can be deemed remanufacturing until FDA issues formal guidance that further clarifies the regulation for everyone – the existing regulations that require 510(k) clearance for remanufactured devices would be a nullity and would apply to no one.

In fact, it is difficult to imagine any example of an operation that more clearly fits the regulation's definition of "remanufacturing." As FDA has explained repeatedly, with the modifications performed, EndoWrists "no longer maintain the same safety and effectiveness profile as cleared with the original manufacturer's own submission" and therefore "require[] additional review to the new labeled usage limit in order to establish safety and effectiveness," Cahoy Dec. Ex. 64 at -5727, because "if the use-life counter is reset or extended past the number of available use lives, then the device specifications are changed," *id.* Ex. 31 at -0335. Even if the Court is disinclined to apply the deference ordinarily accorded FDA in the interpretation of its own regulations and governing statute, *see Young v. Cmty. Nutrition Inst.*, 476 U.S. 974, 981-82 (1986), it should reach the same result for one simple reason: FDA was right.

In short, the business that SIS sought to establish in selling Rebotix's services to remanufacture EndoWrists failed for the simple reason that the governing regulatory regime does not permit that

activity without a regulatory clearance that SIS and Rebotix did not have.[11] SIS is accordingly unable as a matter of law to prove that any action of Intuitive was a proximate cause of its alleged injury.

Numerous courts have confirmed that a plaintiff cannot establish antitrust injury if it could not legally engage in the economic activity that it claims the defendant prevented it from pursuing. For example, in *Modesto*, the plaintiff, an irrigation district, complained that PG&E had interfered with its attempt to offer competing electric service in Pittsburg. The district court held that the plaintiff could not prove antitrust injury because it "possessed neither the legal right, nor the necessary [regulatory agency] permission to expand its services into Pittsburg." 309 F. Supp. 2d at 1170. And "[b]ecause [the plaintiff's] conduct was unlawful by its own terms, PG&E's response – however anti-competitive or seemingly monopolistic – could not inflict an cognizable antitrust injury." *Id.* The Ninth Circuit affirmed, confirming that, because it was "not a lawful competitor," the plaintiff "could not have suffered an antitrust injury at the hands of PG&E." 158 F. App'x at 807; *see also In re Wellbutrin XL*, 868 F.3d at 165 ("It is not enough for the Appellants to show that Anchen wanted to launch its drug; they must also show that the launch would have been legal.").

Similarly here, necessary regulatory clearance was lacking for the activity SIS claims Intuitive blocked it from pursuing; it accordingly cannot prove antitrust injury.

2. SIS's Motion for Partial Summary Judgment on Intuitive's Counterclaims and Unclean Hands Defense Should Be Denied.

SIS's motion seeks partial summary judgment on Intuitive's counterclaims and unclean hands affirmative defense "as they relate to FDA."[12] SIS argues that the Court should hold that its statements that FDA clearance was not required cannot be deemed false or misleading, either because the truth was ambiguous or because the Court lacks authority to hold otherwise. But as discussed in Section III.A.1

[11] The courts in the Florida lawsuits brought by Rebotix and Restore declined to rule on whether entities modifying EndoWrists to bypass their use counters needed FDA clearance – although they also barred the parties' FDA experts from testifying on that "legal" question. *See* Cahoy Dec. Ex. 71 at 6-8, 16, Ex. 72 at 8-9. SIS speculates that the *Rebotix* court may have been concerned that FDA might change its mind after the agency told Rebotix it could request an appealable order. *See* SIS Mot. at 21 n.13. There is no evidence Rebotix ever made such a request.

[12] Intuitive's counterclaims and affirmative defenses identify other false or misleading statements by SIS; those are not the subject of SIS's motion. Nor does Intuitive's cross-motion seek summary judgment on those claims.

above, the truth was *not* ambiguous. There may be *other* situations, involving *other* processes applied to *other* medical devices, in which the application of the regulations on remanufacturing would be a close call – but this is not one of them.

As for the Court's authority, SIS acknowledges, as it must, that the Supreme Court has held that Lanham Act claims "can coexist with FDA's enforcement and regulatory authority," SIS Mot. at 19 (citing *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 115 (2014)). And SIS can point to no post-*POM* authority – in this circuit or elsewhere – in which a court has declined to accept a Lanham Act claim under circumstances in which (a) there are applicable binding regulations and (b) the agency has taken a consistent view over the course of many years confirming the application of those regulations to the very activity at issue. No one here is asking the Court to issue a decision that would "implicate the FDA's rulemaking authority" or make "an original determination" about the legal requirements applicable to remanufacturing. SIS Mot. at 20 (citations omitted). The applicable regulations are already on the books. Nor do Intuitive's counterclaims ask the Court to contradict FDA's judgment on the issues presented here.

SIS offers little argument in support of its motion on the unclean hands defense. It merely asserts that it "cannot be said to have acted 'willfully' when FDA doesn't even know what standards it will enforce…." SIS Mot. at 22-23. But FDA does know what the standard is and has both published the standard in regulations and communicated its application to EndoWrists on numerous occasions. SIS's motion does not proffer evidence that it was innocently unaware of this.

B. Intuitive's Conduct Was Supported By Legitimate Justifications.

1. Intuitive Had Legitimate Justifications for Measures to Comply With Its Regulatory Obligations, and FDA Agreed.

SIS's antitrust claims fail for the additional reason that Intuitive's challenged conduct was supported by legitimate justifications. Under each of SIS's theories, Intuitive's conduct can be found to violate the antitrust laws *only* if it injured competition and was not supported by non-pretextual justifications. *American Express*, 138 S. Ct. at 2284.[13] As the Supreme Court has explained, a plaintiff

[13] This framework applies to all of SIS's claims, including those under Section 1 for tying and exclusive dealing, as well as those under Section 2. *Brantley v. NBC Universal, Inc.*, 675 F.3d 1192, 1197 (9th Cir. 2012); *Fed. Trade Comm'n v. Qualcomm Inc.*, 969 F.3d 974, 991, 1003 (9th Cir. 2020); *see also Ill.*

must first show that the challenged restraint has a substantial anticompetitive effect that harms consumers in a relevant market, after which "the burden shifts to the defendant to show a procompetitive rationale for the restraint. If the defendant makes this showing, then the burden shifts back to the plaintiff to demonstrate that the procompetitive efficiencies could be reasonably achieved through less anticompetitive means." *Id.* The alternative must be "a significantly (not marginally) less restrictive means for achieving the same procompetitive benefits." *NCAA v. Alston*, 141 S. Ct. 2141, 2164 (2021); *see also Epic Games, Inc. v. Apple Inc.*, 559 F. Supp. 3d 898, 1040 (N.D. Cal. 2021). The analysis of SIS's Section 2 claims is "essentially the same." *Qualcomm*, 969 F.3d at 991. Courts can review claims under Sections 1 and 2 simultaneously, and "if … [the] court finds that the conduct in question is not anticompetitive under § 1, the court need not separately analyze the conduct under § 2." *Id.*

For multiple reasons, including those discussed above, injury to lawful competition – and resulting antitrust injury to SIS – does not exist here. But even if SIS could carry its threshold burden, its claims would fail because the undisputed facts show that Intuitive's conduct was supported by legitimate justifications.

It is important to recognize at the outset that SIS *cannot* challenge the use limits themselves. Without a use counter that disabled an EndoWrist after it reached its approved use limit, there would have been nothing to "reset" and SIS's hoped-for business could not exist. SIS's but-for world must therefore assume that the use limits are justified and lawful, or it would have no claim. In any event, the undisputed facts establish that Intuitive had legitimate reasons for designing its instruments as it did.

The antitrust laws will not condemn a defendant that had a "reasonable basis to conclude that its [challenged] actions were necessitated by concrete factual imperatives recognized as legitimate by the regulatory authority." *Phonetele, Inc. v Amer. Tel. & Tel. Co.*, 664 F.2d 716, 737-38 (9th Cir. 1981); *see Cont'l T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 55 n.23 (1977) (recognizing as legitimate justifications arising from federal and state laws requiring "that manufacturers assume direct responsibility for the safety and quality of their products"); *Taylor v. Volkswagen of Amer., Inc.*, 2009

Tool Works Inc. v. Indep. Ink, Inc., 547 U.S. 28, 42 (2006) (rule of reason applies to claims involving patented products).

WL 1011631 (W.D. Wash. Apr. 14, 2009) (granting summary judgment where restrictions were justified by, *inter alia*, ensuring that vehicles met certification standards of the countries in which sold).[14] This principle derives from an understanding that "the proper role of antitrust courts is to accommodate the peculiar circumstances under which regulated entities operate." *Phonetele*, 664 F.2d at 743.[15]

There is no evidence to rebut Intuitive's showing that it had a "reasonable basis" for concluding that EndoWrist use limits were needed – and that FDA, as the governing regulatory authority, agreed. The regulatory regime governing Class II medical devices like EndoWrists requires a manufacturer to demonstrate that its devices are subject to "special controls," evaluated through the 510(k) process, that provide a reasonable assurance of safety and effectiveness. 21 U.S.C. § 360c(a)(1)(B); *see* Cahoy Dec. Ex. 10 ¶¶ 35-37, 143-47. For EndoWrists, those measures include the use limits, which were (a) designed to address a known vulnerability of the instruments, (b) supported by extensive testing, and (c) carefully reviewed by FDA over the course of more than two decades. After reviewing these submissions, FDA cleared the instruments as "limited use" devices. Rosa Dec. ¶ 31; Cahoy Dec. Ex. 10 ¶¶ 75-101. That the use limits were justified by the existing technical record, and regarded as such by FDA, was reinforced when FDA insisted to prospective remanufacturers that their attempts to tamper with those limits required a full new round of testing and FDA clearance. *See* pp. 6-8 above.

Moreover, the determination that use limits were needed, the evaluation of methods through which they should be determined and implemented, and the accompanying fundamental design choices for EndoWrists all occurred more than two decades ago, long before there was any suggestion that third parties might try to "compete" by hacking the devices. Rosa Dec. ¶ 27, 29-32. They were adopted at a

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[14] *See also In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 12 (1st Cir. 2020) (regulatory justification defense can defeat antitrust claim if defendant's decision was reasonable and made in good faith); *S. Pac. Commc'ns Co. v. Amer. Tel. & Tel. Co.*, 740 F.2d 980, 1009-10 (D.C. Cir. 1984) (same); *cf. Robertson v. Sea Pines Real Est. Cos.*, 679 F.3d 278, 292 (4th Cir. 2012) (challenged restrictions "may serve to ensure compliance with state regulations … rather than to exclude lower-priced competition"); *In re Wyoming Tight Sands Antitrust Cases*, 1990 WL 155542, at *3 (D. Kan. Sept. 6, 1990) ("evidence of regulatory compliance" relevant to whether challenged activities were procompetitive).

[15] Most courts, including the Ninth Circuit, characterize a defendant's regulatory compliance as a "defense" rather than a source of blanket immunity. *E.g.*, *Phonetele*, 664 F.2d at 737. It is therefore discussed here under the justification defense prong of the Supreme Court's standard test.

time when Intuitive was a new entrant struggling to convince customers to accept a brand-new technology, *id.* ¶ 23, and could have had *no* market power that would allow it to force buyers to accept unwanted restrictions, Smith Dec. Ex. 1 ¶¶ 115, 119. Given these facts, no credible claim of pretext could be made. *See Epic Games*, 559 F. Supp. 3d at 1038 (upholding asserted justifications where the plaintiff failed to show them to be pretextual).

Nor can SIS carry its burden of demonstrating the existence of a substantially less restrictive alternative that would be "virtually as effective" and could be implemented "without significant increased cost." *Id.* at 1041 (citation omitted). Intuitive was under no obligation to adopt the "least restrictive alternative" in designing its products. *Alston*, 141 S. Ct. at 2161 ("[A]ntitrust law does not require businesses to use anything like the least restrictive means of achieving legitimate business purposes," and "courts should not second-guess degrees of reasonable necessity so that the lawfulness of conduct turns upon judgments of degrees of efficiency."). The most SIS can offer is its expert's speculation that Intuitive might have designed EndoWrists to apply *different* criteria to manage use on an individual basis, such as the period of time the instrument is in active use and the force with which it is applied during surgery. But this is pure theory on his part; he does not identify a *practical* way to implement it in a working instrument. (Intuitive's *Daubert* motion on this expert is at Dkt. No. 120.) And since no such design exists, he can offer no basis to conclude that such a design – even if it worked and even if its safety could be verified – would consistently require EndoWrists to be replaced substantially less often, making the use limits substantially less restrictive.

Given the legitimacy of the use limits (as demonstrated by FDA clearance of EndoWrists as "limited use" devices), Intuitive's efforts to ensure that the limits were not circumvented, including the letters sent to customers, are supported by the same justifications. Those letters, which stressed the absence of required FDA clearance for the remanufacturing that was occurring and the associated patient safety implications, furthered Intuitive's general obligation to ensure that its products (including the da Vinci systems to which the remanufactured EndoWrists were attached) were operated in full compliance with FDA requirements. They also fulfilled Intuitive's broader duty to take reasonable steps to protect against injuries that could arise from misuse of its products. *See, e.g.*, *Hiner v. Deere & Co.*, 340 F.3d

1190, 1193-94 (10th Cir. 2003); *Lewis v. Tallahassee*, 2006 WL 231291, at *2 (N.D. Fla. Jan. 30, 2006); *Wright v. Stang Mfg. Co.*, 54 Cal. App. 4th 1218, 1235 (1997).

For this independent reason, summary judgment should be entered for Intuitive on SIS's antitrust claims.

2. Intuitive's Introduction of New Products and Product Enhancements Does Not Violate the Antitrust Laws.

SIS also asserts that Intuitive violated the antitrust laws by (a) introducing new, improved versions of its da Vinci systems, the X and Xi, that require use of more advanced X/Xi EndoWrists (thus reducing potential demand for remanufactured S/Si EndoWrists) and (b) by using encryption for the wireless technology used in those EndoWrists (which makes them more difficult to hack). Dkt. No. 1 ¶¶ 107-109. In essence, SIS complains that Intuitive should have refrained from continuing to innovate, because the resulting product improvements disadvantaged SIS as a potential competitor.

Courts are "properly very skeptical" about claims that competition has been harmed by a firm's product design changes. *Allied Orthopedic Appliances, Inc. v. Tyco Health Care Grp. LP*, 592 F.3d 991, 998 (9th Cir. 2010) (quoting *United States v. Microsoft*, 253 F.3d 34, 65 (D.C. Cir. 2001)). As the Ninth Circuit has explained, the success of a firm through "the process of invention and innovation" is not unlawful under the antitrust laws, and "a design change that improves a product by providing a new benefit to consumers does not violate Section 2 absent some associated anticompetitive conduct." *Id.* at 998-99. Every firm, even an alleged monopolist, "has 'the right to redesign its products to make them more attractive to buyers.'" *Id.* at 999 (quoting *Foremost Pro Color, Inc. v. Eastman Kodak Co.*, 703 F.2d 534, 545 (9th Cir. 1983)). This is true even if the improvement "is performed by a monopolist and harms competitors as a result." *Id.* at 999-1000. As the Ninth Circuit further explained, "[t]here is no room in this analysis for balancing the benefits or worth of a product improvement against its anticompetitive effects. If a monopolist's design change is an improvement, it is 'necessarily tolerated by the antitrust laws.'" *Id.* at 1000 (quoting *Foremost Pro Color*, 703 F.2d at 545).

It is undisputed that the X/Xi systems and X/Xi EndoWrists improved Intuitive's product offerings. Examples of specific innovations include better vision for the doctor and better access to the patient. Cahoy Dec. Ex. 2 at 27:23-29:2, 136:18-137:22. As a result of the improved technology, the

newer X and Xi systems can be used for a broader set of procedures than the older S and Si systems. *Id.* Ex. 51 at 97:17-98:6, Ex. 74 at 61:13-62:9.

SIS has no evidence to support its allegation that "Intuitive has taken steps to force customers to switch" from earlier generation S/Si systems to the newer generation X/Xi systems. *See* Dkt. No. 1 ¶ 108. To the contrary, the record confirms that migration to the X/Xi systems is due to hospital demand for what those systems can offer. Hospitals – including the plaintiffs in the companion case here – chose to switch to X/Xi systems specifically because of the innovations they embody. *See* Cahoy Dec. Ex. 47 at 118:3-6 (Franciscan switched to the Xi because its physicians wanted the improved technology), Ex. 51 at 15:8-16:8, 59:5-13 (Valley head of surgery advocated for the upgrade because of the technological improvements).

SIS's claim is not bolstered by the fact that Intuitive has announced that in 2024 – a full ten years after the new generation system was introduced – it will be ceasing support for the old S/Si systems. A similar argument – that a manufacturer must indefinitely maintain support for old technology that benefits competitors – was rejected in *Allied*. There, the plaintiff argued that the defendant could have made its monitors compatible with old sensors defendant sold, allowing the plaintiff to continue to sell parts for the monitors. *Allied*, 592 F.3d at 1002. The Ninth Circuit easily rejected the argument: "Our precedents make clear that a monopolist has no duty to help its competitors survive or expand when introducing an improved product design." *Id.*

Allied also forecloses SIS's allegations that discounts induced consumers to purchase Intuitive's products. Dkt. No. 1 ¶ 109. As in *Allied*, SIS can identify no way in which discounts Intuitive provided to customers independently violated the antitrust laws. *Allied*, 592 F.3d at 1002. That is unsurprising, as it is almost never an antitrust violation to offer a customer lower prices.

SIS also alleges that Intuitive's upgrade to wireless technology in X/Xi EndoWrists, and the associated encryption, was done for the "sole purpose" of "prevent[ing] competition in repair [sic] services," by preventing "third parties such as SIS from accessing the counter." Dkt. No. 1 ¶ 107. There is no evidence that Intuitive had SIS (or remanufacturers in general) in mind when it designed X/Xi EndoWrists more than a decade ago, much less that encryption was adopted for the "sole purpose" of

thwarting them. As this Court has already recognized, to pursue this claim SIS must prove that Intuitive had no procompetitive justification for its design change. *See* Dkt. No. 69 at 2; *see also Allied*, 592 F.3d at 998-1002. This it cannot do.

The undisputed evidence shows (a) that X/Xi EndoWrists were upgraded to include a wireless communication system for transmitting information, including use counts, between the EndoWrist and the Xi system and (b) that this upgrade necessitated new cybersecurity protections, because information sent through an unencrypted wireless channel can be remotely intercepted. *See* pp. 11-12 above. FDA has published several guidance documents emphasizing the need for device makers to account for such cybersecurity issues in the clearance process. *See* Cahoy Dec. Exs. 87, 88. Citing to such guidance, FDA instructed Intuitive in August 2013 to respond to questions about cybersecurity as part of the X/Xi clearance process, and Intuitive identified encryption as a key mitigation measure against modification or injection of false instrument data that could lead to incorrect motion control and use of instruments beyond their tested life. *See id.* Ex. 10 at ¶¶ 246-54, Ex. 85 at ¶ 52, Ex. 90 at -6542.

SIS's expert (who is the subject of a pending *Daubert* motion) does not dispute that encryption was needed to comply with regulatory requirements for the use of wireless technology in Xi EndoWrists. Instead, he argues that Intuitive should not have upgraded to wireless technology in the first place. *Id.* Ex. 89 ¶¶ 22-23. But wireless connections have significant benefits over wired connections, including improved consistency and reliability. *See* Rosa Dec. ¶ 37; Cahoy Dec. Ex. 5 at 27:20-28:8. Even SIS's expert has confirmed that consistency issues with wired connections present valid considerations for product design. *See* Cahoy Dec. Ex. 86 at 98:13-24. The upgraded wireless chip had other undisputed benefits as well. *See id.* Ex. 10 at ¶ 56, Ex. 86 at 97:21-98:2, 112:10-115:17. SIS thus cannot meet its burden to show that the change to wireless technology presented no improvement over the previous generation. *See Allied*, 592 F.3d at 1000. (recognizing "'the undesirability of having courts oversee product design'" and that "'any dampening of technological innovation would be at cross-purposes with antitrust law'" (quoting *United States v. Microsoft Corp.*, 147 F.3d 935, 948 (D.C. Cir. 1998)).

C. SIS's Lanham Act Claim Against Intuitive Fails Because the Sole Remaining Challenged Statement Is Neither False Nor Misleading.

SIS's sole remaining Lanham Act claim following the Court's Order on Intuitive's motion to dismiss (Dkt. No. 70 at 9) rests on its assertion that Intuitive, in correspondence with SIS customers, "misrepresented that SIS's services are contrary to FDA approvals of the EndoWrist products." Dkt. No. 1 ¶¶ 123-24; *see also* Cahoy Dec. Exs. 82, 83. As demonstrated above, the services SIS was selling *were* contrary to the FDA clearances, so the statements were true.

Moreover, SIS's own arguments about the regulatory regime amount to, at most, a theory that the law is ambiguous. *See* SIS Mot. at 20 ("This is not a situation where statutory and regulatory provisions are 'clear in the relevant respects….'" (citation omitted)). While SIS is wrong about that, its position that the law remains unresolved is alone sufficient to defeat its Lanham Act claim, because interpretations of ambiguous law are statements of opinion, not fact. *Coastal Abstract Serv., Inc. v. First Amer. Title Ins. Co.*, 173 F.3d 725, 731 (9th Cir. 1999) ("Absent a clear and unambiguous ruling from a court or agency of competent jurisdiction, statements by laypersons that purport to interpret the meaning of a statute or regulation are opinion statements … not generally actionable under the Lanham Act.").

Finally, SIS possesses no evidence of consumer deception, a "critical" showing for any Lanham Act claim in which literal falsity cannot be shown. *See William H. Morris Co. v. Grp. W, Inc.*, 66 F.3d 255, 258 (9th Cir.), *supplemented*, 67 F.3d 310 (9th Cir. 1995) (explaining "critical" need for evidence of deception where statements are not literally false); *Apple Inc. v. Amazon.com, Inc.*, 915 F. Supp. 2d 1084, 1090-91 (N.D. Cal. 2013) (entering summary judgment absent such evidence).

IV. CONCLUSION

For the reasons set forth above, the Court should enter summary judgment for Intuitive on SIS's Complaint in its entirety and deny SIS's motion for partial summary judgment.

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